REMARKS

Applicants' have amended Claim 1 to add a further proviso to more clearly define Applicants' invention. Applicants assert that no new matter has been added and that support for this proviso may be found throughout the specification.

Claims 1-22 are pending in this case. Claims 1-10 are compound claims. Claim 11 is a composition claim. Claims 12 – 22 claim the use of the compounds and composition of claims 1-11. All claims are subject to the Examiners Restriction Requirement. For the reasons given below, Applicants respectfully traverse this restriction requirement and request reconsideration. However, in order to advance the prosecution of this case and to comply with the requirement to fully respond to the Restriction Requirement even though it is traversed, Applicants elect to prosecute the subject matter of Group I and elect 6-(3,5-Dichloropyridin-4-yl)-2-[[4-(diethylaminocarbonyl)phenyl]-amino]-8-methyl-8*H*-pteridin-7-one as the single species for prosecution on the merits.

Applicants' Invention

Applicants invention claims compounds containing 2-amino-pteridin-7-one moieties, compositions containing them and the use of these compounds and compositions to treat proliferative disorders.

Examiner's Lack of Unity Rejection

In the Office Action, the Examiner set forth thirty-two groups of claims alleging that each invention or group of inventions are not linked to form a single general inventive concept under PCT Rule 13.1. The groups set forth by the Examiner are noted below:

Group I, Claim(s) 2, 4, 5 and parts of 1, 8, 9, and 11, drawn to 2-amino-pteridin-7-one compounds and compositions.

Group II, Claim(s) 3, and parts of 1, 8, 9, and 11, drawn to 2-amino-pteridin-7-dione compounds and compositions.

Group III, Claim(s) 6, and parts of 1, 8, 9, and 11, drawn to 2-amino-5,6-dihydro-pteridine compounds and compositions.

Group IV, Claim(s) 7, 10, and parts of 1 and 11, drawn to 2-amino-7-ureido-pteridine compounds and compositions.

Group V, Claim(s) parts of 1 and 11, drawn to 2-thio, 2-sulfoxo- and 2-sulfonyl-pteridin-7-one compounds and compositions.

Group VI-X, Claim(s) parts of 12, 21 and 22, drawn to treating each of the five different disease listed in claim12.

Group XI, Claim(s) 14 and part of 13, drawn to inhibiting cdc2.

Group XII, Claim(s) 15 and part of 13, drawn to inhibiting cdk2.

Group XIII, Claim(s) 16 and part of 13 drawn to inhibiting cdk6.

Group XIV, Claim(s) 18 and part of 17 drawn to inhibiting PDGF.

Group XV, Claim(s) 19 and part of 17 drawn to inhibiting FGF.

Group XVI, Claim(s) 20 drawn to treating vascular diseases.

Group XVII-XXXII, Claim(s) parts of 22, drawn to treating each of the additional sixteen listed diseases of claim 22 not provided for in Groups VI-X.

37 CFR 1.475 provides the requirements for a lack of unity invention. 37 CFR 1.475 (a) provides that

> "... a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement for unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution that each of the claimed inventions, considered as a whole, makes over the prior art."

MPEP §1.475 (a)

Unity of Invention vs Novelty Rejection

The examiner alleges that the inventions listed in Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.3 because they lack the same or corresponding special technical features. According to the Examiner "the technical feature of claim 1 are the compounds of the formula listed in the claim." (OA, Page 3, paragraph 3) The Examiner alleges that ". . . many such compounds of formula I are known, including those taught in Ott (Chem. Ber.)". . . . "Compound I, page 340 fits the formula of claim 1 with R^2 = methyl, W = sulfur, R^4 = dimethylamino, $R^6 = R^8$ =hydrogen". (OA, Page 3, paragraph 3) Applicants respectfully submit that the reference to Ott Compound I on page 340 is inapplicable to Applicants' claimed invention. In Ott's Compound I, R is the equivalent of Applicants WR^2. R in Ott Compound 1 is hydrogen. In Applicants' Formula I, W is not hydrogen. Therefore, Compound 1 of Ott has no equivalent to Applicants' W.

The Examiner's rejection for lack of unity is based on his assertion that "the formula of claim 1 . . . is not novel." (OA, Page 3, paragraph 3) The Examiner has improperly rejected Claim 1 (by stating that "the formula of claim 1 . . . is not novel.") without issuing a proper rejection of claim 1 under 37 CFR 1.104. Specifically MPEP 707.07(d) states that "Where a claim is refused for <u>any</u> reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated, and the word "rejected" <u>must</u> be used." (emphasis added) In a telephone interview with the Examiner and his Supervisor, Examiner Shah, the Examiner stated that he had not rejected claim 1. However, in the absence of such a rejection of claim 1, the application of a reference, such as Ott et al. to negate a special technical feature, is not proper without utilization of such reference to reject the claim.

Applicants respectfully submit that requiring restriction of an application for Lack of Unity of Invention should be based on <u>having more than one invention in an application</u>, not on whether the claims in themselves are novel.

The examiner further asserts that 37 CFR 1.475 (b) subsection (2) limits applicants to a patent for "[a] product and process of use of said product". The examiner interprets this section to include "one single product and one single use of that product."

In making the restriction requirement for several claims, the Examiner has improperly divided single claims into different inventions. It is the inventors' position to define what they

believe to be their invention and to set this forth in a claim to that invention. The Examiner's requirement to divide one claim, for instance claim 22, into 20 different inventions is an improper restriction. Similarly, the Examiner has also divided parts of claims 1, 8, 9, and 11 into different groups as applying to different inventions.

The Examiner's UOI rejection for all claims, including claim 22, for which he defined 20 different groups into which claim 22 must be divided (Groups XVII – XXXII and Groups VI – X) is improper. Applicants do not understand how a single claim can have a UOI rejection because the claims define the invention. In the case of claim 22, the invention is directed to a number of alternative uses of the 2-amino-pteridin-7-one compounds of the present invention.

35 U.S.C. § 121 provides:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

Therefore, the statute allows restriction where there are two or more inventions within an application. The statute does not provide for restriction where there are allegedly two or more inventions within a claim, as attempted herein by the Examiner. Claims, by their very nature cover multiple inventions, indeed all generic claims by definition cover multiple inventions. It is not proper to require restriction within a single claim merely because it contains multiple inventions. If this was true, there could be no such thing as a generic claim.

While § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not however, provide a basis for an examiner to reject a particular claim on that same basis.

Applicants respectfully submit that the Examiner has not explained why the 2-amino-pteridin-7-one compounds of Applicants' invention are independent and distinct inventions. For the reasons provided above, Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

Applicants invite the Examiner to call the undersigned if a telephone interview would advance the prosecution.

Respectfully submitted,

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